Statement-II

The Number of VIALS of Anti-RHD immonoglobulin (Batch No. 6/88) produced Distributed and subsequently withduced by M/s. Bharat Serum, and Vaccines Pvt. Ltd.

Strength	Production (No. of vials)	Distributed (No. of vials)	Withdrawn by the firm (No. of vials)
100 mcg	339	240	75
250 mcg	442	228	57
350 mcg	383	383	165
400 mcg	819	463	18

SHRI ANAND SHARMA: My question is ...(*Interruptions*)... no screening the blood was done ...(*interruptions*).

Have you segregated the patients. Have you identified the people injected. If so, I want to know whether the vaccine produced by the Bharat Serums and Vaccines Ltd. was subjected to Elisa test and Western blot test. If not, how was the certification allowed. (*Interruptions*)

12.00 NOON.

KUMARI SAROJ KHAPARDE: The firm have been asked to immediately stop manufacture and distribution of all such products and also to recall from the market all the anti-D immunoglobulin products manufactured by this firm. Action in the form of stoppage of production and distribution has already been taken.

MR. CHAIRMAN: Question Hour is over.

Now Papers to be laid on the Table.

WRITTEN ANSWERS TO QUESTIONS

Sale of anti-RHD vaccine containing AIDS anti-bodies at the AIIMS, Super Bazar Unit

*82. SHRI GURUDAS DAS GUPTA:
SHRI PARVATHANENI UPENDRA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the presence of the AIDS anti-bodies was discovered in the anti-RHD vaccine sold by the Super Bazar Unit in the All India Institute of Medical Sciences (AIIMS), New Delhi;

(b) if so, the details thereof; and

(c) what action was taken for its withdrawal from the market and also against the company which manufactured this Vaccine?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) Two samples of injection anti-D immunoglobulin of batch No. 6|88 produced by M|s. Bharat Serums and Vaccines Pvt. Ltd., tested at the All India Institute of Medical Sciences were found positive for HIV anti-bodies.

The Commissioner, Food and Drugs Administration, Maharashtra took steps to stop further production and distribution of all blood products by the firm and to recall from the market all the stocks of anti-D immunoglobulin injections.

The Drug Controller of Delhi took action to freeze stocks of batch No. 6|88 of anti-D immunoglobulin injections.

Particulars of the distribution of batch No. 6|88 were given to the State Drug Controllers and they were requested to take steps to freeze the stocks and also to ensure withdrawal of stocks from Government Hospitals and nursing homes.